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(54) **METHOD FOR TIBIAL NAIL INSERTION**

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 A61B 17/72 (2006.01)
 A61B 17/56 (2006.01)
(52) **U.S. Cl.**
 CPC *A61B 17/725* (2013.01); *A61B 17/56* (2013.01); *A61B 17/72* (2013.01); *A61B 2017/564* (2013.01)
(58) **Field of Classification Search**
 CPC A61B 17/1717; A61B 17/72–17/748; A61B 17/56; A61B 2017/564
 USPC 606/62–68
 See application file for complete search history.

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(57) **ABSTRACT**

A method for implanting a longitudinal intramedullary nail into the tibia comprises inserting the tibia nail along a plane of symmetry through the tuberositas tibiae. Thereby, the tuberositas tibiae can be used during nail insertion to correctly align the nail and the target arm to the symmetry plane of the bone. This means, that the whole construct, the nail attached to the target arm, has to be inserted in external rotation.
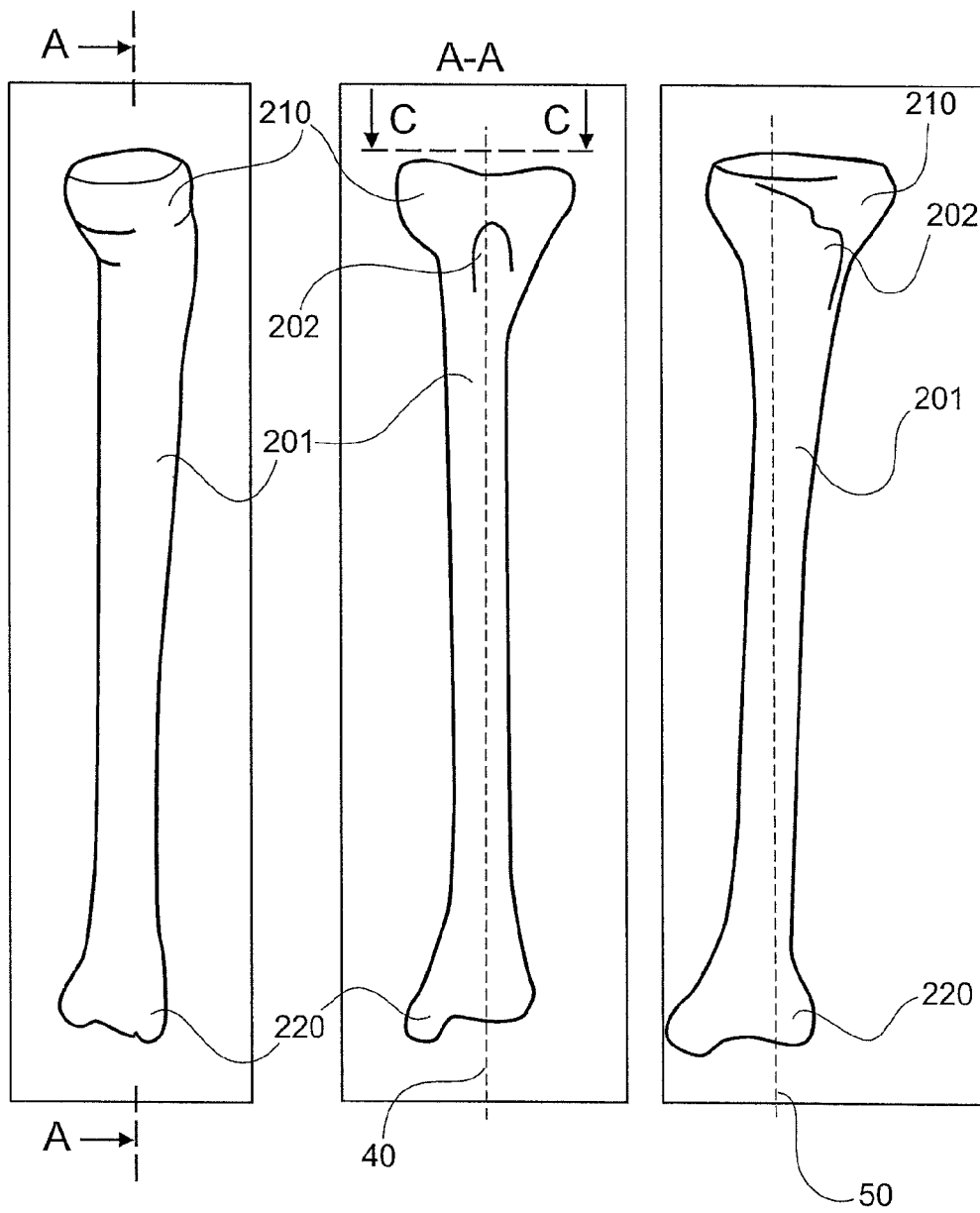
20 Claims, 4 Drawing Sheets

A →

A-A

210

↓C   C↓
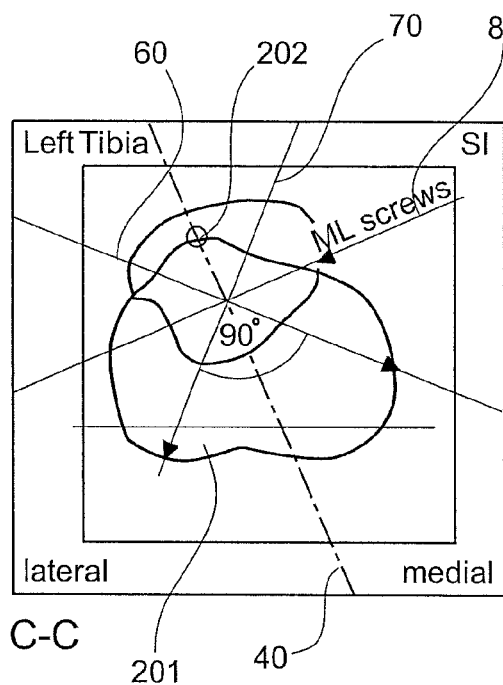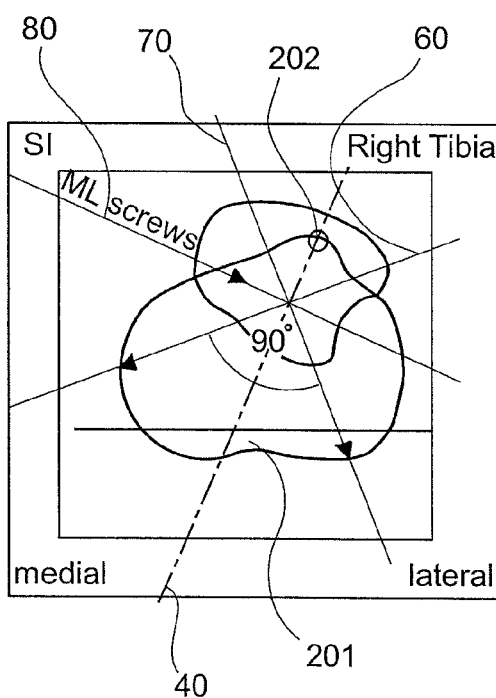
202

201

220

40

A →

Fig. 1

210

202

201

220

50
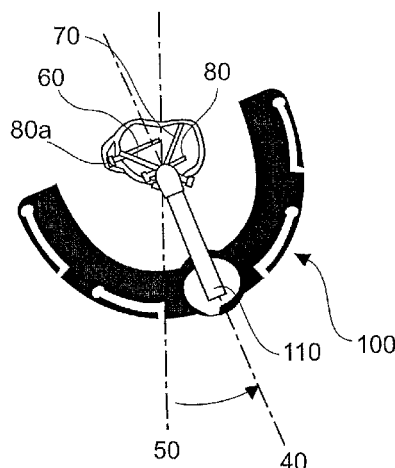
Fig. 2

Fig. 3

Fig. 4

Fig. 5

Fig. 8

Fig. 9

Fig. 6

Fig. 7

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                    ┌─────────────────────┐
                    │     Providing an    │
                    │  intramedullary nail│
                    └─────────────────────┘
                       ╱              ╲
                      ╱                ╲
                     ╱         ┌──────────────────┐
                    ╱          │   Identifying a  │
                   ╱           │ sagittal plane of│
          ┌──────────────────┐ │     a tibia      │
          │   Identifying a  │ └──────────────────┘
          │ tuberositas tibiae│         │
          │      plane       │          ▼
          └──────────────────┘ ┌──────────────────┐
                   │           │  Aligning the nail│
                   ▼           │ to the sagittal   │
          ┌──────────────────┐ │      plane        │
          │  Aligning the nail│ └──────────────────┘
          │      to the      │          │
          │ tuberositas tibiae│          ▼
          │      plane       │ ┌──────────────────┐
          └──────────────────┘ │ Externally rotating│
                   ╲           │     the nail      │
                    ╲          └──────────────────┘
                     ╲                 ╱
                      ╲               ╱
                     ┌──────────────────┐
                     │    Inserting     │
                     │     the nail     │
                     └──────────────────┘
                              │
                              ▼
                     ┌──────────────────┐
                     │    Inserting     │
                     │  locking screws  │
                     └──────────────────┘
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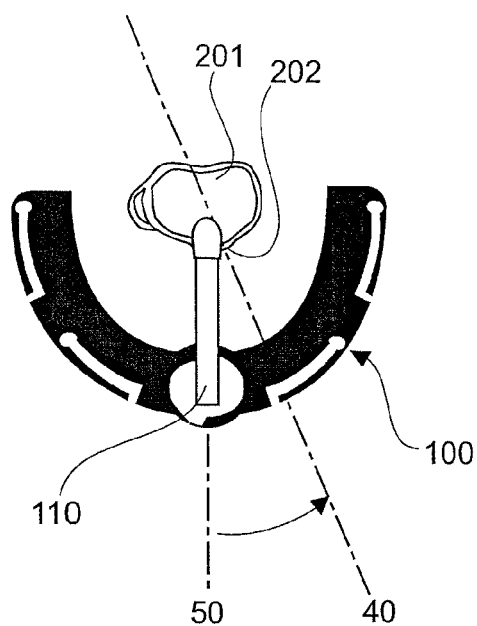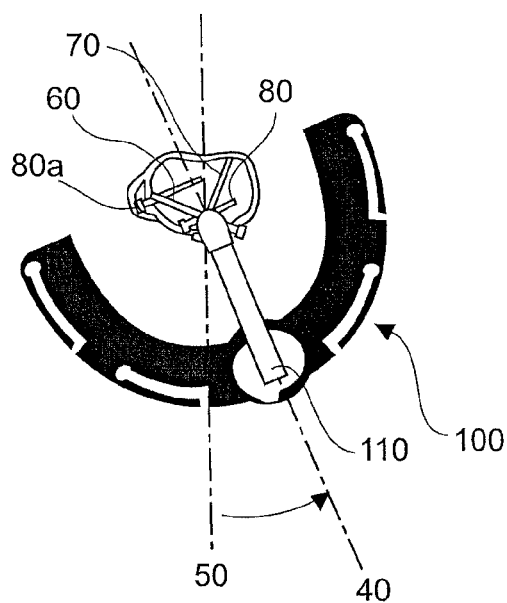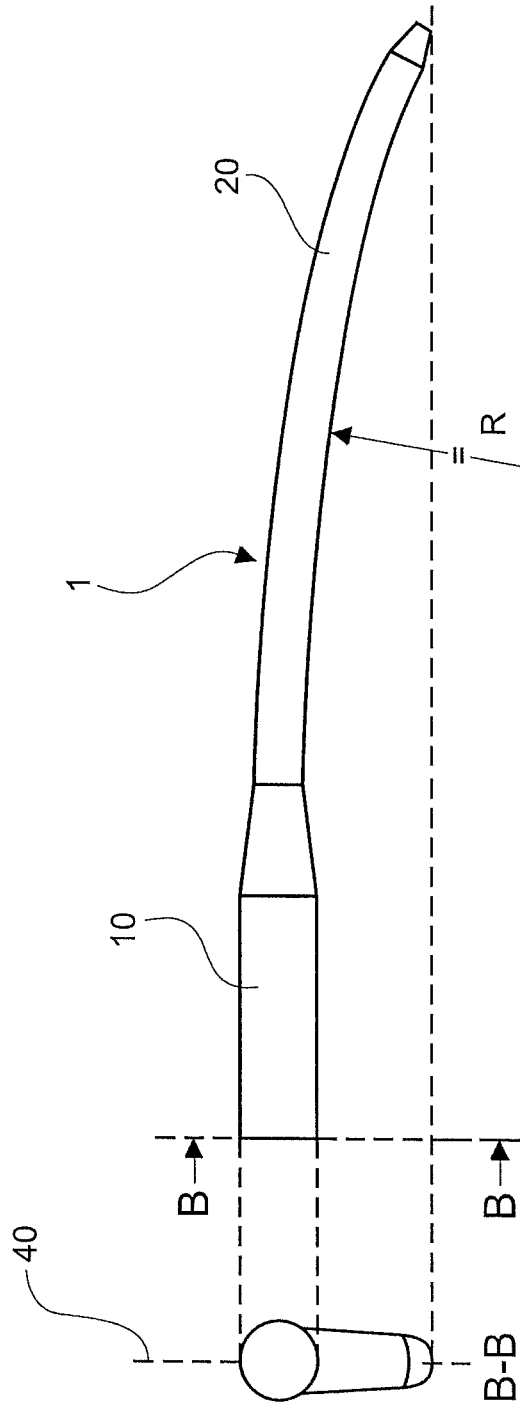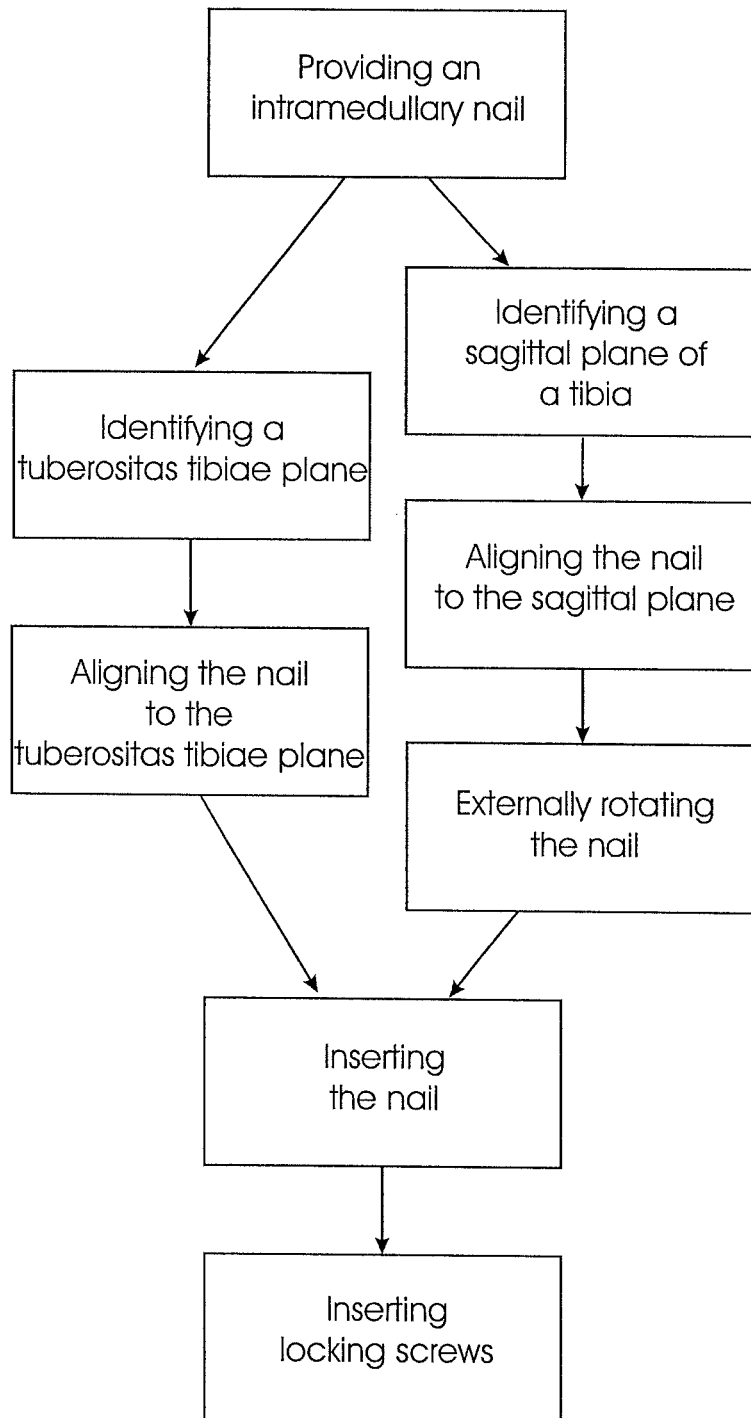
Fig. 10

METHOD FOR TIBIAL NAIL INSERTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 13/234,629 filed Sep. 16, 2011, the disclosure of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The invention generally relates to methods for tibial nail insertion. In particular, the invention relates to a method for implanting a longitudinal intramedullary nail into a tibia.

Tibial nailing often requires intensive hammering during insertion which might cause iatrogenic fractures.

Getting the rotation correct after intramedullary nailing is a clinical challenge, especially for the femur. However, tibial malrotation after intramedullary nailing is likely more common than reported. The cases of three patients who incurred symptomatic rotational deformities after closed intramedullary nailing are reported in Kevin M. Kahn, MD, et al. "Malrotation after locked intramedullary tibial nailing: Three case reports and review of the literature" (The Journal of TRAUMA, Vol. 53, Number 3, pages 549 to 552). Today, the rotation of a fractured tibia is compared to its non-fractured counterpart, respectively. The rotation is generally evaluated measuring the difference in torsion. The range of acceptable malrotation may be less than 15 degrees.

However, the shape of the tibia is unique. The tibia may have a rotational mismatch between its proximal and distal ends and the ankle joint is externally rotated relative to the proximal part of the tibia (Hideki Mizu-uchi et al. "The effect of ankle rotation on cutting of the tibia in total knee arthroplasty" (The Journal of Bone & Joint Surgery 2006; 88:2632-2636)).

For a better understanding, it is noted that the proximal end of the bone is the end of the bone being oriented toward the heart of the human body. The distal end of the bone is the end of the bone being oriented away from the heart of the human body. An intramedullary nail may be a tibia nail, wherein the intramedullary nail comprises a non-driving end and a driving end. The non-driving end is the end of the nail which firstly enters the intramedullary channel of a bone. Entering a bone from the proximal end of the bone is denoted as antegrade entering. Entering a bone from the distal end of the bone is denoted as retrograde entering. Consequently, a nail adapted to be implanted from the proximal end of the tibia may be denoted as antegrade tibial nail.

A tuberositas tibiae plane is a plane defined by the tuberositas tibiae, i.e. the tip most protruding to the front at the proximal end of the tibia, the entry point into the medullary channel and the axis of the medullary channel inside the tibia. Furthermore, the sagittal plane related to the tibia means a vertical plane orientated from the front to the back (anteroposterior) in a natural position of the leg relative to the chest of a human, for example when the lower leg is tensionlessly placed on a table surface with the toes orientated upwardly. Accordingly, the tuberositas tibiae plane is slightly inclined, i.e. externally rotated approximately between 13 degrees and 37 degrees relative to the sagittal plane.

BRIEF SUMMARY OF THE INVENTION

A smoother nail design with obtuse bends or even curvatures instead of acute-angled bends may provide improved insertion characteristics, avoid hammering and thus improve the clinical outcome.

Trying to understand the anatomy of the tibia is the key to facilitate the nailing procedure and optimize the surgical technique. None of the common three anatomical planes, not even the sagittal plane, can be used to divide the tibia into two symmetric halves.

In morphologic investigations with regard to distinctive landmarks, a tuberositas tibiae plane, that is a natural symmetry plane of the tibia has been identified. The cross section around the diaphysis forms an irregular triangle. The symmetry plane runs through the triangle's cone end represented by the tuberositas tibiae (TT) and it's elevated continuation to the distal part.

The idea is to insert tibia nails along the described tuberositas tibiae plane. Thereby, the tuberositas tibiae can be used during nail insertion to correctly align the plane of the nail containing the radius of the curved nail portion and the target arm to the symmetry plane of the bone. This means, that the whole construct, the nail attached to the target arm, has to be inserted in external rotation.

In a further study, it has been determined that a nail with a retro-curved axis, a constant radius of curvature would optimally fit the medullary canal, if the nail is inserted according to the above-described procedure. This radius of curvature in the natural symmetry plane of the tibia extends between 2000 mm and 3000 mm (preferably 2500 mm). Either a constant radius or any approximation (due to straight driving and non-driving ends with tangential connections to the curved part) within the given radius of curvature range would fit the medioposterior curvature of the tibia.

In summary, nailing the tibia along its medioposterior symmetry plane will offer the following benefits:

1) The approach permits not only a design for a dedicated left and a dedicated right nail, but also a universal design for combined left and right nails with an either constant retro-curved radius or a smooth connection between the established Herzog bend of the nail, its shaft and possible distal bend. The smooth design in turn may improve the insertion characteristics significantly, avoid intensive hammering and iatrogenic fractures which remains to be verified.

2) Owing to the triangular shaped tibia shaft, drilling for all proximal and distal mediolateral screws will be carried out more perpendicular to the medial cortex preventing sliding of the drill.

3) Additionally, the drilling and locking procedure will be simplified for the surgeon due to the laterally orientated target arm and thus the external dislocation of the operating field with better accessibility.

4) In case of a universal nail design for a combined left and right nail, all screws in the tibial plateau have to be placed symmetric to the longitudinal nail axis at an angle of between and 50 degrees, preferably a 45 degrees angle between both proximal screws and symmetric plane, in order to guarantee that their tips penetrate the cortex in equivalent spots but at slightly different heights if the whole construct is rotated left and right. These new screw trajectories in the tibial plateau also reduce the risk of penetrating the tibiofibular joint.

5) Furthermore, this principle is considered to be used for control, restoration and adjustment of the correct rotation. Obviously, there seems to be a dependency between the natural rotation of the ankle and the natural symmetry plane of the tibia defined by the tuberositas tibiae. The idea is to use this correlation to control the rotation. This landmark-based approach, i.e. orienting the tuberositas tibia to the natural external rotation of the ankle during

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fracture reduction, is not geared to the healthy contra lateral side and will potentially be more accurate, reduce operation room time and thus improve the clinical outcome. The technique of the present invention is thus not geared to the healthy contra lateral side and will potentially be more accurate, reduce operation room time and thus improve the clinical outcome.

According to a first embodiment of the invention, a method for implanting a longitudinal intramedullary nail into the tibia, comprises the steps of providing a longitudinal intramedullary nail having a section with a curvature, which curvature has a predetermined radius; identifying the tuberositas tibiae plane; aligning the intramedullary nail, such that the radius of the intramedullary nail lies in the tuberositas tibiae plane; and inserting the intramedullary nail into a marrow (medullary) channel of the tibia.

According to an embodiment of the invention, the intramedullary nail is an intramedullary tibia nail. According to another embodiment of the invention, the radius of the nail is between 2000 mm and 3000 mm. The radius may also be between 2400 mm and 2600 mm. Furthermore, the radius may be about 2500 mm.

The curvature of the intramedullary nail section may correspond to a curvature of the marrow channel of the tibia into which the intramedullary nail is to be inserted. Accordingly, it depends on the actual anatomy of the fractured tibia what radius of the tibia nail should be preferred.

According to a further embodiment of the invention, the method further comprises the step of placing screws in a tibia plateau at the proximal end of a tibia into which the intramedullary nail is to be inserted in an angle of for example 40 degrees to 50 degrees, depending on the actual position and orientation of transverse holes in the proximal portion of the intramedullary nail.

According to a second embodiment of the invention, a method for implanting a longitudinal intramedullary nail into the tibia, comprises providing a longitudinal intramedullary nail having a section with a curvature, which curvature has a predetermined radius; identifying a sagittal plane of the tibia; aligning the intramedullary nail, such that the radius of the intramedullary nail lies in a plane being inclined externally rotated by an angle between 13 degrees to 37 degrees with respect to the sagittal plane of the tibia; and inserting the intramedullary nail into a marrow (medullary) channel of the tibia, wherein the intramedullary nail may be an intramedullary tibia nail.

According to an embodiment of the invention, the angle is between 17 degrees and 33 degrees. The angle may also be between 21 degrees and 26 degrees. Furthermore, the angle may be about 24 degrees. It will be understood, that the angle of rotation differs due to the actual anatomy of a specific tibia.

The curvature of the intramedullary nail section may correspond to a curvature of the marrow channel of the tibia into which the intramedullary nail is to be inserted.

Also with respect to this aspect of the invention, the radius may be between 2000 mm and 3000 mm. The radius may also be between 2400 mm and 2600 mm. Furthermore, the radius may be about 2500 mm.

According to an embodiment of the invention, the method further comprises the step of placing screws in a tibial plateau of a tibia into which the intramedullary nail is to be inserted in an angle of for example 40 degrees to 50 degrees, depending on the actual position and orientation of transverse holes in the proximal portion of the intramedullary nail.

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These aspects defined above and further aspects, features and advantages of the present invention can also be derived from the examples of the embodiments to be described hereinafter and are explained with reference to the examples of the embodiments to which the invention is not limited.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be detailed by way of exemplary embodiments with reference to the attached drawings.

FIG. 1 shows an example of a left tibia viewed in a lateral to medial direction.

FIG. 2 shows a left tibia with a tuberositas tibiae plane perpendicular to the drawing sheet.

FIG. 3 shows a left tibia with a sagittal plane perpendicular to the drawing sheet.

FIG. 4 shows a top view of a proximal end of a left tibia.

FIG. 5 shows a top view of a proximal end of a right tibia.

FIG. 6 is a side view of a tibia nail according to the invention.

FIG. 7 is a front view of a tibia nail according to the invention.

FIG. 8 is a top view of a target arm relative to a tibia plateau.

FIG. 9 is a top view is the rating an orientation of a target arm during an insertion according to the invention.

FIG. 10 is a flowchart of embodiments of a method according to the invention.

It is noted that the illustration of the drawings is only schematically and not to scale. In different figures, similar elements are provided with the same reference signs.

DETAILED DESCRIPTION

In the following, FIGS. 1 to 5 are described illustrating specific anatomic aspects of a tibia and orientations of these aspects at a tibia, relevant for the understanding of the invention.

FIG. 1 shows the outer contour of a tibia bone 201 with a proximal end 210 of the tibia and a distal end 220 of the tibia. The tibia in FIG. 1 is shown substantially from a medio-lateral direction.

As indicated by the arrows A-A in FIG. 1, the tibia in FIG. 2 is shown substantially from the front (anterior), wherein the tibia 201, in this view, includes a tuberositas tibiae 202. Furthermore, the tuberositas tibiae plane 40 extending through the tuberositas tibiae 202 is indicated in FIG. 2.

In FIG. 3 the tibia is shown together with a sagittal plane 50. The tibia 201 includes proximal end 210, tuberositas tibiae 202, and distal end 220.

FIG. 4 is a view in the direction C-C (as indicated in FIG. 2), i.e. a top view on the proximal end of a left tibia. FIG. 5 is a top view on the proximal end of a right tibia. In both figures, the tuberositas tibiae plane 40 is shown extending through tuberositas tibiae 202. Furthermore, possible screw insertion directions 60, 70 for locking screws to be introduced into the proximal end of an intramedullary nail are shown. Furthermore, a screw insertion direction 80 for a medio-lateral (ML) screw is shown. A second screw 80a may be inserted in the ML direction which is parallel to direction 80.

FIGS. 6 and 7 are views of an intramedullary nail, i.e. of a tibia nail, in accordance with the invention. The tibia nail 1 includes a proximal end portion 10 and a distal end portion 20, wherein the distal end portion 20 is curved with a radius R. The curvature along the central axis of the nail lies in a single plane. In FIG. 7, the tuberositas tibiae plane 40 is

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additionally shown. It can be seen from FIGS. 6 and 7, that the curvature of the nail is formed within one plane. The radius R is between 2000 and 3000 mm.

FIGS. 8 and 9 show a tibia 201 together with a targeting device 100 comprising a targeting arm 110. In FIG. 8, targeting arm 110 is orientated parallel to a sagittal plane 50 of the tibia. Closely beside an end 52 of the targeting arm, the tuberositas tibiae 202 is visible. In FIG. 9, the targeting arm 110 of the targeting device 100 is rotated about the angle α so that the targeting arm is now orientated parallel to the tuberositas tibiae plane 40. With the targeting device in an orientation relative to the tibia as shown in FIG. 9, a tibia nail may be introduced into the medullary channel of the tibia, in accordance with the invention.

Further shown in FIG. 9 are locking screws, two of which orientated in a medio-lateral direction, denoted with reference sign 80. Further screws may be introduced inclined with respect to that direction, wherein these further screws may be orientated perpendicular relative to each other, as indicated in FIGS. 4 and 5.

The flowchart in FIG. 10 illustrates the principle of the steps performed in accordance with the invention. It will be understood that the steps described, are major steps, wherein these major steps might be differentiated or divided into several sub-steps. Furthermore, there might be also sub-steps between these major steps. Therefore, a sub-step is only mentioned if this step may be important for the understanding of the principles of the method according to the invention.

In a first step, a longitudinal intramedullary nail 1 having a curved section is provided wherein the curvature has a predetermined radius as discussed above.

In a next step, in accordance with a first embodiment of the invention, the tuberositas tibiae plane is identified. This identification is performed by firstly identifying the tuberositas tibiae and the entry point into the medullary channel on the upper surface of the tibia, and secondly by identifying the axis of the medullary channel. The tuberositas tibiae, the entry point as well as the axis of the medullary channel lie on the tuberositas tibiae plane.

The intramedullary nail is aligned in a following step, such that the radius of the curved section of the intramedullary nail lies in the tuberositas tibiae plane.

Alternatively, in accordance with a second embodiment of the invention, a sagittal plane of the tibia is identified.

Then, the intramedullary nail is firstly aligned with the sagittal plane, i.e. the radius of the intramedullary nail lies in the sagittal plane, and secondly is externally rotated by an angle between 13 degrees to 37 degrees with respect to the sagittal plane orientation of the tibia previously determined.

In a subsequent step, the intramedullary nail is inserted into a marrow channel of the tibia through an entry point in the tibial plateau.

Finally, screws may further be placed in a tibia plateau of the tibia into which the intramedullary nail is to be inserted. The actual position and orientation of each screw depends on the actual design of the driving end portion of the intramedullary nail. Finally, further locking screws are inserted through transverse bores in the non-driving end portion of the nail, so that the distal portion of the tibia may be reliably fixed relative to the proximal portion of the tibia.

While the invention has been illustrated and described in detail in the drawings and afore-going description, such illustrations and descriptions are to be considered illustrative or exemplary and not restrictive, the invention is not limited to the disclosed embodiments.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practising the claimed invention, from a study of the drawings, the disclosure and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality.

The mere fact that certain measures are recited and mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

The invention claimed is:

1. A method for implanting a longitudinal intramedullary nail into the tibia, the method comprises:
   providing a longitudinal intramedullary nail having a section with a curvature, which curvature has a predetermined radius;
   identifying a sagittal plane of the tibia;
   aligning the intramedullary nail, such that the radius of the intramedullary nail lies in the sagittal plane,
   externally rotating the intramedullary nail until the intramedullary nail is inclined by an angle between 13° to 37° with respect to the sagittal plane of the tibia; and
   inserting the intramedullary nail into a marrow channel of the tibia.

2. The method of claim 1, wherein the inclined angle is between 17° and 33°.

3. The method of claim 1, wherein the inclined angle is between 21° and 26°.

4. The method of claim 1, wherein the inclined angle is about 24°.

5. The method of claim 1, wherein the curvature of the intramedullary nail section corresponds to a radius of curvature of a marrow channel of the tibia into which the intramedullary nail is to be inserted.

6. The method of claim 5, wherein the radius of curvature is between 2000 mm and 3000 mm.

7. The method of claim 6, wherein the radius of curvature is between 2400 mm and 2600 mm.

8. The method of claim 7, wherein the radius of curvature is about 2500 mm.

9. The method of claim 1, further comprising placing screws through a proximal portion of the intramedullary nail and into a tibia plateau of a tibia after the intramedullary nail is inserted.

10. A method for implanting a longitudinal intramedullary nail into the tibia, the method comprises:
    providing a longitudinally extending intramedullary nail having a section with a curvature, which curvature has a predetermined radius of curvature lying along a plane containing the longitudinal axis of the nail;
    identifying a sagittal plane through a tibia;
    aligning the intramedullary nail prior to insertion, such that the plane containing the radius of the intramedullary nail section lies in the sagittal plane;

externally rotating the intramedullary nail until the plane containing the nail radius is coplanar with a plane through a tuberositas tibiae of the tibia; and thereafter, inserting the intramedullary nail into a marrow channel of the tibia through an entry point lying on the plane through the tuberositas tibiae.

11. The method as set for in claim **10** wherein the external rotation is between 13° and 37° with respect to the sagittal plane.

12. The method of claim **11**, wherein the external rotation is between 17° and 33° with respect to the sagittal plane.

13. The method of claim **12**, wherein the external rotation is between 21° and 26° with respect to the sagittal plane.

14. The method of claim **13**, wherein the external rotation is about 24° with respect to the sagittal plane.

15. The method of claim **10**, wherein the curvature of the intramedullary nail section corresponds to a radius of curvature of a marrow channel of the tibia into which the intramedullary nail is to be inserted.

16. The method of claim **15**, wherein the radius of curvature is between 2000 mm and 3000 mm.

17. The method of claim **16**, wherein the radius of curvature is between 2400 mm and 2600 mm.

18. The method of claim **17**, wherein the radius of curvature is about 2500 mm.

19. The method of claim **10**, further comprising placing screws through a proximal portion of the intramedullary nail and into a tibia plateau of a tibia after the intramedullary nail is inserted.

20. A method for implanting a longitudinal intramedullary nail into the tibia, the method comprises:

providing a longitudinally extending intramedullary nail having a section with a curvature lying in a plane, which curvature has a predetermined radius measured from a center lying in the plane;

identifying a sagittal plane of the tibia;

aligning the intramedullary nail, such that the plane containing the radius of curvature of the intramedullary nail lies in the sagittal plane;

externally rotating the intramedullary nail until the plane of the intramedullary nail containing the radius is inclined by an angle between 13° to 37° with respect to the sagittal plane of the tibia; and

inserting the intramedullary nail into a marrow channel of the tibia.

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